



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10052 and CMS-10629]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by **[INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>
2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10052 Recognition of Pass-Through Payment for Additional (New) Categories of Devices
under the Outpatient Prospective Payment System and Supporting Regulations

CMS-10629 Waiver Application for Providers and Suppliers Subject to an Enrollment Moratorium

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Reinstatement with change of a currently approved collection; *Title of Information Collection:* Recognition of Pass-Through Payment for Additional (New) Categories of Devices under the Outpatient Prospective Payment System and Supporting Regulations; *Use:* Section 402 of the Benefits Improvement and Protection Act of 2000 (BIPA), enacted on December 21, 2000, made changes in the provision for transitional pass-through payment for devices under the hospital OPPI. Section 402 of BIPA amended section 1833(t)(6) of the Act to require that we abandon the item-specific approach in determining the eligibility of medical devices for transitional pass-through payments. This provision mandated that we adopt a category approach for making such payments. In accordance with this requirement, we would pay for any device that falls in categories we establish for this purpose. This provision required us to establish the initial set

of categories, to include devices previously determined eligible for transitional pass-through payments, effective April 1, 2001.

The law made clear that application and approval processes are no longer required as the basis for determining an individual medical device's eligibility for transitional pass-through payments. However, we must assemble certain crucial information to be able to determine the appropriateness of establishing an additional (new) category. The information that we seek to collect is essential to determine whether additional categories of medical devices are appropriate for transitional pass-through payments. The intent of these provisions is to ensure that timely beneficiary access to new technologies is not jeopardized by inadequate payment levels.

Interested parties such as hospitals, device manufacturers, pharmaceutical companies, and physicians apply for transitional pass-through payment for certain items used with services covered in the outpatient PPS. After we receive all requested information, we evaluate the information to determine if the creation of an additional category of medical devices for transitional pass-through payments is justified. We may request additional information related to the proposed new device category, as needed. We advise the applicant of our decision, and update the outpatient PPS during its next scheduled quarterly payment update cycle to reflect any newly approved device categories.

Form Number: CMS-10052 (OMB control number: 0938-0857); *Frequency:* Yearly; *Affected*

Public: State, Local, or Tribal Governments; *Number of Respondents:* 10; *Total Annual Responses:*

10; *Total Annual Hours:* 160. (For policy questions regarding this collection contact AuSha

Washington at 410-786-3736.)

2. *Type of Information Collection Request:* Extension of a currently approved collection;

Title of Information Collection: Waiver Application for Providers and Suppliers Subject to an

Enrollment Moratorium; *Use:* The Provider Enrollment Moratoria Access Waiver Application,

named the “Waiver Application for Providers and Suppliers Subject to an Enrollment Moratorium” has been created to collect that data, which will be completed by providers and suppliers to apply for a waiver in Moratoria locations. CMS will be collecting this data on an ad-hoc basis until the Paperwork Reduction Act Submission has been approved. The goal of the Waiver Application for Providers and Suppliers Subject to an Enrollment Moratorium is to provide a uniform application process that all providers and suppliers may follow so that CMS is able to administer the Medicaid or Children’s Health Insurance Program moratorium process in a standardized and repeatable manner. This form creates a standardized process so that moratoria decisions are being made with the same criteria each time. *Form Number:* CMS-10629 (OMB control number: 0938-1313); *Frequency:* Occasionally; *Affected Public:* Federal Government, State, Local, or Tribal Governments; *Number of Respondents:* 800; *Total Annual Responses:* 800; *Total Annual Hours:* 6. (For policy questions regarding this collection contact Kim Jung at 410-786-9370.)

Dated: March 7, 2019.

William N. Parham, III,

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

[FR Doc. 2019-04490 Filed: 3/11/2019 8:45 am; Publication Date: 3/12/2019]